

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

JOYCE JUSTUS,

Plaintiff,

v.

Civil Action No. 2:12-cv-00956

ETHICON, INC., ET AL.,

Defendant.

MEMORANDUM OPINION AND ORDER  
*(Defendants' Motion for Summary Judgment)*

Pending before the court is a Motion for Summary Judgment [ECF No. 115] filed by defendants Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon") against plaintiff Joyce Justus. As set forth below, the defendants' Motion is **GRANTED in part** and **DENIED in part**.

**I. Background**

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 58,000 cases currently pending, approximately 28,000 of which are in the Ethicon MDL. In an effort to efficiently and effectively manage this massive MDL, the court decided to conduct pretrial discovery and motions practice on an individualized basis so that once a case is trial-ready (that is, after the court

has ruled on all summary judgment motions, among other things), it can then be promptly transferred or remanded to the appropriate district for trial. To this end, the court ordered the plaintiffs and defendant to submit a joint list of 200 of the oldest cases in the Ethicon MDL that name only Ethicon, Inc., Ethicon, LLC, and/or Johnson & Johnson. These cases became part of a “wave” of cases to be prepared for trial and, if necessary, remanded. *See* Pretrial Order No. 193, *In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-002327, Aug. 19, 2015, *available at* <http://www.wvsc.uscourts.gov/MDL/ethicon/orders.html>. Plaintiff’s case was selected as a Wave 1 case.

Ms. Justus was surgically implanted with Prolift on April 29, 2008 at Mission Hospital in Asheville, North Carolina by Doctor Nancy S. Howden. Am. Short Form Compl. ¶¶ 9–12 [ECF. No. 21]. She is a resident of North Carolina. *Id.* ¶ 4. Ethicon moves for summary judgment on all of Ms. Justus’ substantive claims. Defs.’ Mem. Supp. Mot. Summ. J. 1 [ECF No. 116].

## **II. Legal Standards**

### **A. Summary Judgment**

To obtain summary judgment, the moving party must show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not “weigh the evidence and determine the truth of the matter.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most

favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some “concrete evidence from which a reasonable juror could return a verdict in his [or her] favor.” *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere “scintilla of evidence” in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Dash v. Mayweather*, 731 F.3d 303, 311 (4th Cir. 2013); *Stone v. Liberty Mut. Ins. Co.*, 105 F.3d 188, 191 (4th Cir. 1997).

## **B. Choice of Law**

Under 28 U.S.C. § 1407, this court has authority to rule on pretrial motions in MDL cases such as this. The choice of law for these pretrial motions depends on whether they involve federal or state law. “When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. When considering questions of state law, however, the transferee court must apply the state law that would have applied to the individual cases had they not been transferred for

consolidation.” *In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996) (internal citations omitted). In cases based on diversity jurisdiction, the choice-of-law rules to be used are those of the states where the actions were originally filed. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir. 1996) (“Where a transferee court presides over several diversity actions consolidated under the multidistrict rules, the choice of law rules of each jurisdiction in which the transferred actions were originally filed must be applied.”); *In re Air Crash Disaster Near Chi., Ill.*, 644 F.2d 594, 610 (7th Cir. 1981); *In re Digitek Prods. Liab. Litig.*, No. 2:08-md-01968, 2010 WL 2102330, at \*7 (S.D. W. Va. May 25, 2010).

If a plaintiff files her claim directly into the MDL in the Southern District of West Virginia, however, I consult the choice-of-law rules of the state in which the implantation surgery took place. *See Sanchez v. Boston Scientific Corp.*, 2:12-cv-05762, 2014 WL 202787, at \*4 (S.D. W. Va. Jan. 17, 2014) (“For cases that originate elsewhere and are directly filed into the MDL, I will follow the better-reasoned authority that applies the choice-of-law rules of the originating jurisdiction, which in our case is the state in which the plaintiff was implanted with the product.”). Ms. Justus filed this case in the Western District of North Carolina and it was transferred to the Southern District of West Virginia by order of the United States Judicial Panel on Multidistrict Litigation. Conditional Transfer Order [ECF No. 3]. Thus, the choice-of-law principles of North Carolina guide this court’s choice-of-law analysis.

The parties agree, as does this court, that these principles compel application of North Carolina law. For tort claims, North Carolina generally applies the *lex loci delicti* approach, which provides that “the state where the injury occurred is considered the situs of the claim.” *Harco Nat’l Ins. Co. v. Grant Thornton LLP*, 698 S.E.2d 719, 722–23 (N.C. Ct. App. 2010). Here, the alleged injury occurred in North Carolina, where Ms. Justus was implanted with the allegedly defective device. Thus, I apply North Carolina’s substantive law to the tort claims in this case. For warranty claims, North Carolina applies the “most significant relationship” approach, which “requires the forum to determine which state has the most significant relationship to the case.” *Boudreau v. Baughman*, 368 S.E.2d 849, 853–54 (N.C. 1988). North Carolina courts have found that “the place of sale, distribution, delivery, and use of the product, as well as the place of injury . . . to be the state with the most significant relationship to the warranty claims.” *Id.* at 855–56. Thus, I also apply North Carolina’s substantive law to the warranty claims in this case.

### III. Analysis

Ethicon moves for summary judgment on all of the plaintiff’s substantive claims. Ms. Justus does not contest this motion with regard to strict products liability,<sup>1</sup> negligent manufacturing, negligent misrepresentation, negligent infliction of emotional distress, breach of implied warranty for a particular purpose, unjust

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<sup>1</sup> The plaintiff’s Amended Short Form Complaint does not allege any strict liability claims. Am. Short Form Compl. ¶ 13. However, Ethicon moves for summary judgment to the extent that the plaintiff’s claims for failure to warn, manufacturing defect, and design defect might be deemed to assert strict liability claims. Defs.’ Mot. Summ. J. ¶ 1. The plaintiff agrees that she will not pursue claims based on strict liability. Pl.’s Resp. ¶ 1 [ECF No. 129].

enrichment, common law fraud, fraudulent concealment, and constructive fraud. Pl.’s Mem Supp. Resp. 4 n.2 [ECF No. 130]. Ethicon’s Motion for Summary Judgment is **GRANTED** as to those claims.

Ms. Justus opposes Ethicon’s motion with regard to negligence, negligent failure to warn, negligent design, breach of express warranty, breach of implied warranty of merchantability, violation of consumer protection laws, and gross negligence.<sup>2</sup> Below, I apply the summary judgment standard to each remaining claim.

#### **A. Negligent Failure to Warn**

Under North Carolina law, “[n]o manufacturer . . . shall be held liable in any product liability action for a claim based upon inadequate warning or instruction unless the claimant” can satisfy three requirements. N.C. Gen. Stat. § 99B-5(a). First, the claimant must establish “that the manufacturer . . . acted unreasonably in failing to provide such warning or instruction.” *Id.* Second, the claimant must establish “that the failure to provide adequate warning or instruction was a proximate cause of the harm for which damages are sought.” *Id.* Finally, the claimant must establish either of the following:

- (1) At the time the product left the control of the manufacturer . . . , the product, without an adequate warning or instruction, created an unreasonably dangerous condition that the manufacturer . . . knew, or in the exercise of ordinary care should have known, posed a substantial risk of harm to a reasonably foreseeable claimant[; or]
- (2) After the product left the control of the manufacturer . . . , the manufacturer or seller became aware of or in the exercise of ordinary care should have known that the product posed a substantial risk of harm to a reasonably

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<sup>2</sup> Ethicon does not address Count XVII (punitive damages) or Count XVIII (discovery and rule tolling). I do not make any rulings as to those claims. Ethicon challenges several specific claims sounding in negligence, but plaintiff points out that Ethicon does not separately challenge Count I (negligence). I do not make any rulings as to any negligence claims beyond those discussed below.

foreseeable user or consumer and failed to take reasonable steps to give adequate warning or instruction or to take other reasonable action under the circumstances.

*Id.*

Ethicon argues that, under subsection (c) of the same statute, the learned intermediary doctrine shields it from liability. Defs.’ Mem. Supp. Mot. Summ. J. 9 (citing N.C. Gen. Stat. § 99B-5(c)). Subsection (c) provides:

“[N]o manufacturer or seller of a prescription drug shall be liable in a products liability action for failing to provide a warning or instruction directly to a consumer if an adequate warning or instruction has been provided to the physician or other legally authorized person who prescribes or dispenses that prescription drug for the claimant . . . .”

N.C. Gen. Stat. § 99B-5(c).

While I am not persuaded that the plain language of subsection (c) provides the basis for application of the learned intermediary doctrine to the instant case, “[t]here are indications that North Carolina courts would adhere to the learned intermediary doctrine” in matters of product liability. *Baraukas v. Danek Med., Inc.*, No. 6:97CV00613, 2000 WL 223508, at \*4 (M.D.N.C. Jan. 13, 2000) (citing *Foyle ex rel. McMillan v. Lederle Labs.*, 674 F. Supp. 530, 535–36 (E.D.N.C. 1987)). In fact, in *Baraukas*, the United States District Court for the Middle District of North Carolina determined that the learned intermediary doctrine applied where the manufacturer warned the plaintiff’s physician about bone screws. *Id.* Accordingly, consistent with the courts that have addressed this issue before me, I assess Ms. Justus’ negligent failure to warn claim under the learned intermediary doctrine.

Here, I **FIND** that genuine disputes of material fact exist with regard to: (1) whether Ethicon's warning was adequate; and (2) whether the alleged inadequate warning proximately caused the alleged harm to Ms. Justus. Therefore, Ethicon's Motion for Summary Judgment on the plaintiff's negligent failure to warn claim is **DENIED**.

### **B. Negligent Design**

Under North Carolina law, a plaintiff alleging inadequate design first must prove "that at the time of its manufacture the manufacturer acted unreasonably in designing or formulating the product, [and] that this conduct was a proximate cause of the harm for which damages are sought . . . ." N.C. Gen. Stat. § 99B-6(a). To determine whether Ethicon acted unreasonably in designing the Prolift, North Carolina requires that the following factors be considered:

- (1) The nature and magnitude of the risks of harm associated with the design or formulation in light of the intended and reasonably foreseeable uses, modifications, or alterations of the product[;]
- (2) The likely awareness of product users, whether based on warnings, general knowledge, or otherwise, of those risks of harm[;]
- (3) The extent to which the design or formulation conformed to any applicable government standard that was in effect when the product left the control of its manufacturer[;]
- (4) The extent to which the labeling for a prescription or nonprescription drug approved by the United States Food and Drug Administration conformed to any applicable government or private standard that was in effect when the product left the control of its manufacturer[;]
- (5) The utility of the product, including the performance, safety, and other advantages associated with that design or formulation[;]
- (6) The technical, economic, and practical feasibility of using an alternative design or formulation at the time of manufacture[;]
- (7) The nature and magnitude of any foreseeable risks associated with the alternative design or formulation.

*Id.* § 99B-6(b). Additionally, a plaintiff must prove one of the following:



(1) At the time the product left the control of the manufacturer, the manufacturer unreasonably failed to adopt a safer, practical, feasible, and otherwise reasonable alternative design or formulation that could then have been reasonably adopted and that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product[; or] (2) At the time the product left the control of the manufacturer, the design or formulation of the product was so unreasonable that a reasonable person, aware of the relevant facts, would not use or consume a product of this design.

*Id.* § 99B-6(a).

Here, I **FIND** that genuine disputes of material fact exist with regard to: (1) whether Ethicon acted unreasonably in designing the Prolift; and (2) whether Ethicon unreasonably failed to adopt a safer, practical, feasible, and otherwise reasonable alternative design, or whether the design or formulation of the product was so unreasonable that a reasonable person, aware of the relevant facts, would not use it. Therefore, Ethicon's Motion for Summary Judgment on the plaintiff's negligent design claim is **DENIED**.

### **C. Breach of Express Warranty**

Under North Carolina law:

(1) Express warranties by the seller are created as follows:

(a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.

(b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.

(c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

(2) It is not necessary to the creation of an express warranty that the seller use formal words such as “warranty” or “guarantee” or that he have a specific intention to make a warranty, but an affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty.

N.C. Gen. Stat. § 25-2-313. Accordingly, any actionable express warranty under North Carolina law must turn on a statement that is the “basis of the bargain.” North Carolina law provides that a plaintiff need not prove contractual privity for her express warranty claim to survive. *Alberti v. Manufactured Homes, Inc.*, 407 S.E.2d 819, 825 (N.C. 1991) (“[O]ur case law has recognized that a direct contractual relationship in the sale of the product itself is not a prerequisite to recovery for breach of express warranty against the manufacturer.”)

Even if Ms. Justus relied only on Dr. Howden’s medical judgment in deciding to have the Prolift implanted, a reasonable juror could find that Ms. Justus relied on the express warranties of Ethicon as they were provided to Dr. Howden, which formed the basis for Dr. Howden’s medical judgment. *Cf. Michael v. Wyeth, LLC*, No. CIV.A. 2:04-0435, 2011 WL 2150112, at \*9 (S.D. W. Va. May 25, 2011) (denying summary judgment on breach of express warranty because even though “plaintiff testified that she did not rely on any statements made by defendants . . . she did rely upon her doctors’ recommendations,” and as a result, “a presumption arises that [manufacturer’s] affirmations were at least part of the ‘basis of the bargain’ that led plaintiff to ingest [the] drugs”); *Forst v. SmithKline Beecham Corp.*, 602 F. Supp. 2d 960, 972 (E.D. Wis. 2009) (denying summary judgment on express warranty claim where plaintiff did not read drug manufacturer’s labeling but relied upon doctor’s recommendations, and holding that “a reasonable jury could find that [defendant’s]

representations to [doctor], which were then communicated to the [plaintiffs], constitute an affirmation forming a ‘basis of the bargain’ for [plaintiff’s] use of Paxil.”); *Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 602, 625 (E.D. Pa. 2008) (same).

Here, I **FIND** that genuine disputes of material fact exist with regard to: (1) whether an express warranty was made; and (2) whether Dr. Howden, the implanting physician, relied on the express warranty as the “basis of the bargain.” Therefore, Ethicon’s Motion for Summary Judgment on the plaintiff’s breach of express warranty claim is **DENIED**.

#### **D. Breach of Implied Warranty of Merchantability**

Under North Carolina law, “a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind.” N.C. Gen. Stat. § 25-2-314(1). For a good to be “merchantable,” it must

(a) pass without objection in the trade under the contract description; and (b) . . . [be] of fair average quality within the description; and (c) [be] fit for the ordinary purposes for which such goods are used; and (d) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; and (e) [be] adequately contained, packaged, and labeled as the agreement may require; and (f) conform to the promises or affirmations of fact made on the container or label if any.

*Id.* § 25-2-314(2). To establish a claim for breach of implied warranty of merchantability, the plaintiff must demonstrate: “(1) the goods bought and sold were subject to an implied warranty of merchantability, (2) the goods were defective at the time of the sale, (3) the defective nature of the goods caused plaintiff’s injury, and (4)

damages were suffered as a result.” *Goodman v. Wenco Foods, Inc.*, 423 S.E.2d 444, 454 (N.C. 1992).

Because a reasonable juror could determine that Ethicon negligently designed the Prolift, *see supra* Section III.B, a reasonable juror could likewise find that Ethicon breached the implied warranty of merchantability. *See* N.C. Gen. Stat. § 25-2-314(2)(b). Therefore, Ethicon’s Motion for Summary Judgment on the plaintiff’s breach of implied warranty of merchantability claim is **DENIED**.

#### **E. Violation of Consumer Protection Laws**

Ms. Justus alleges a violation of North Carolina’s Unfair and Deceptive Trade Practices Act (“UDTPA”), which governs unfair and deceptive claims. “In order to establish a *prima facie* claim for unfair trade practices, a plaintiff must show: (1) [the] defendant committed an unfair or deceptive act or practice, (2) the action in question was in or affecting commerce, and (3) the act proximately caused injury to the plaintiff.” *Bumpers v. Cmty. Bank of N. Va.*, 747 S.E.2d 220, 226 (2013) (alteration in original) (quoting *Dalton v. Camp*, 548 S.E.2d 704, 711 (2001)); *see also* N.C. Gen. Stat. § 75-1.1. To show proximate cause in a claim stemming from misrepresentation, a plaintiff must demonstrate reliance on the misrepresentation. *Bumpers* 747 S.E.2d at 88. “Whether a trade practice is unfair or deceptive usually depends upon the facts of each case and the impact the practice has in the marketplace.” *Marshall v. Miller*, 276 S.E.2d 397, 403 (1981) (citation omitted). “[T]here is no explicit statutory

requirement of a showing of bad faith . . . [and] the intent or good faith belief of the actor is irrelevant.” *Id.*

Ethicon moves for summary judgment on Ms. Justus’ UDTPA claim, arguing that she cannot show proximate cause because she testified that she did not rely on information in any brochures in deciding to use the Prolift. Ms. Justus puts forth evidence that Ethicon actively withheld facts from her. I **FIND** that there are material questions of fact as to (1) whether Ethicon committed an unfair or deceptive act or practice, and (2) proximate causation. Therefore, Ethicon’s Motion for Summary Judgment on the plaintiff’s consumer protection claim is **DENIED**.

#### **F. Gross Negligence**

The North Carolina Supreme Court has said the following with regard to ordinary negligence and gross negligence:

[T]he difference between the two is not in degree or magnitude of inadvertence or carelessness, but rather is intentional wrongdoing or deliberate misconduct affecting the safety of others. An act or conduct rises to the level of gross negligence when the act is done purposely and with knowledge that such act is a breach of duty to others, i.e., a conscious disregard of the safety of others. An act or conduct moves beyond the realm of negligence when the injury or damage itself is intentional.

*Yancey v. Lea*, 550 S.E.2d 155, 158 (N.C. 2001) (emphasis omitted) (citing *Brewer v. Harris*, 182 S.E.2d 345, 350 (N.C. 1971)).

Ethicon asserts, without elaboration, that Ms. Justus has not presented sufficient evidence to establish the elements of gross negligence. Ms. Justus asserts that there is a dispute of fact as to Ethicon’s conduct. Ethicon’s Reply acknowledges that Ms. Justus asserts Ethicon purposefully withheld knowledge about

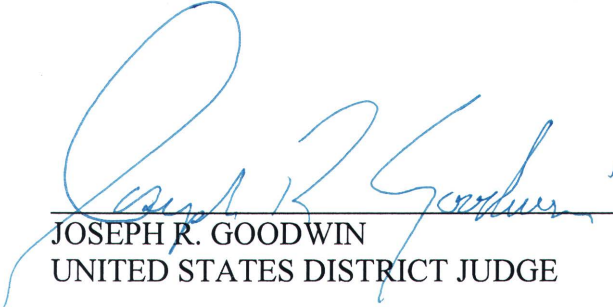
complications associated with the Prolift, but Ethicon argues that Ms. Justus cannot prove this.

Viewing the facts in the light most favorable to Ms. Justus, I **FIND** that there is a material dispute of fact regarding the issue of gross negligence. Therefore, Ethicon's Motion for Summary Judgment on the plaintiff's gross negligence claim is **DENIED**.

#### **IV. Conclusion**

For the reasons discussed above, it is **ORDERED** that Ethicon's Motion for Summary Judgment [ECF No. 115] is **GRANTED in part** and **DENIED in part**. The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: December 21, 2016



JOSEPH R. GOODWIN  
UNITED STATES DISTRICT JUDGE